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| APPLICATION NO.                                | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO      |  |
|--|-----------------|----------------------|---------------------|----------------------|--|
| 09/758,716                                     | 01/11/2001      | Ronald Alan Coffee   | BER-3.5.009/3714    | 1036                 |  |
| 24116  | 7590 06/21/2005 |                      | EXAMINER            |                      |  |
| BATTELLE MEMORIAL INSTITUTE<br>505 KING AVENUE |                 |                      | LEWIS, KIM M        |                      |  |
| COLUMBUS, OH 43201-2693                        |                 |                      | ART UNIT            | ART UNIT PAPER NUMBE |  |
|  | ,               |                      | 3743                |                      |  |

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.  | Applicant(s)  |  |  |  |  |
|--|--|---|--|--|--|--|
| Office Action Summany  | 09/758,716   | COFFEE, RONALD ALAN   |  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit  |  |  |  |  |
| ·  | Kim M. Lewis   | 3743  |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the co  | orrespondence address   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 6(a). In no event, however, may a reply be tim<br>within the statutory minimum of thirty (30) days<br>ill apply and will expire SIX (6) MONTHS from t<br>cause the application to become ABANDONED | ely filed will be considered timely. the mailing date of this communication. (35 U.S.C. § 133). |  |  |  |  |
| Status   |  | •   |  |  |  |  |
| 1) Responsive to communication(s) filed on 22 Fe   | bruary 2005.   |   |  |  |  |  |
| 2a)⊠ This action is <b>FINAL</b> . 2b)☐ This   | This action is FINAL. 2b) This action is non-final.  |   |  |  |  |  |
| 3) Since this application is in condition for allowan  | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is  |   |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |  |   |  |  |  |  |
| Disposition of Claims  |  |   |  |  |  |  |
| 4)⊠ Claim(s) <u>42-67,69-75 and 77-103</u> is/are pending in the application.  |  |   |  |  |  |  |
| 4a) Of the above claim(s) <u>42-46,50-58,60,62-64 and 81-103</u> is/are withdrawn from consideration.  |  |   |  |  |  |  |
| 5)⊠ Claim(s) <u>47-49,59,65-67,69-75 and 77-80</u> is/are allowed.   |  |   |  |  |  |  |
| 6)⊠ Claim(s) <u>61</u> is/are rejected.  |  |   |  |  |  |  |
| 7) Claim(s) is/are objected to.  |  |   |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or  | election requirement.  |   |  |  |  |  |
| Application Papers   |  |   |  |  |  |  |
| 9) The specification is objected to by the Examine   | ·<br>r.  |   |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.   |  |   |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |   |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |   |  |  |  |  |
| 11)☐ The oath or declaration is objected to by the Ex  | aminer. Note the attached Office   | Action or form PTO-152.   |  |  |  |  |
| Priority under 35 U.S.C. § 119   |  | •   |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign  | priority under 35 U.S.C. § 119(a)  | -(d) or (f).  |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  1. ☐ Certified copies of the priority documents have been received.  |  |   |  |  |  |  |
| <ul><li>1. Certified copies of the priority documents have been received.</li><li>2. Certified copies of the priority documents have been received in Application No</li></ul>   |  |   |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |  |   |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |  |   |  |  |  |  |
| * See the attached detailed Office action for a list of  | * **   | d.  |  |  |  |  |
|  |  |   |  |  |  |  |
|  |  |   |  |  |  |  |
| Attachment(s)  |  |   |  |  |  |  |
| 1) Untice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Paper No(s)/Mail Date   |  |   |  |  |  |  |
| ) Notice of Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 5) Notice of Informal Patent Application (PTO-152)   |  |   |  |  |  |  |
| Paper No(s)/Mail Date <u>2/22/05</u> .   | 6) 🛛 Other: <u>Detailed Actio</u>  | <u>on</u> .   |  |  |  |  |

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#### **DETAILED ACTION**

## Response to Amendment

- 1. The amendment filed on 2/7/05 has been received and made of record. As requested the specification and claims 27, 28, 61, 67, 69, 74, 75, 77 and 79 have been amended and claims 1-41, 68 and 76 have been cancelled.
- 2. Claims 42-67, 69-75 and 77-10 are pending in the instant application.

## Information Disclosure Statement

3. The information disclosure statement filed 2/22/05 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

## Election/Restrictions

4. This application contains claims 42-46, 50-58, 60, 62-64 and 81-103 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### 37 CFR 1.132 Declaration

5. The declaration of Dr. Herber S. Bresler under 37 CFR 1.132 filed 2/7/05 is insufficient to overcome the rejection of claim 61 based upon U.S. Patent No. 4,403,331

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("Martin et al."), applied under 35 USC § 103 as set forth in the last Office action because: the declaration recites that,

"Martin is concerned with wettable polymers or small interstices. The quoted recitation of claim 61, in contrast, provides fibres, fibre fragments, or particles which "initiate interactive cellular and/or molecular events". See, ¶ [0016] ("to promote essential cell activities, for example, to stimulate dendritic growth, growth factors such as fibroblast growth factor (FGF), epithelial growth factor (EGF), transforming growth factor (TGF) and others that may be used to promote or otherwise control the sequence of events essential to natural tissue repair") and ¶ [0071] (same quote). In addition, Martin teaches only encouraging clotting which, in turn, promotes tissue repair. The effect of the mat in Martin is, thus, as an indirect promoter of tissue repair. The effect of the mat in Martin is to encourage clotting, to stop bleeding, and perhaps, create an environment which may be favorable to tissue repair. As cited in claim 61, molecular events in tissue repair are initiated directly by the fibers, fibrils, or particles. Thus, new tissue is generated, at the molecular level, due to the presence of the formed fiber, fibrils, or particles."

However, the examiner contends that even if the accomplished feat of promoting tissue repair is an indirect result of applying the dressing of Martin et al. to a wound of user, the claimed limitation of initiating interactive cellular and/or molecular events in tissue repair is nevertheless accomplished. Additionally, the declarant states the claim 61 cites molecular event in tissue repair are initiated directly by the fibers, fibrils, or particles, however, term "directly" does not appear in the claim.

#### Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 7. Claim 61 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,403,331 ("Martin et al.").

As regards claim 61, Martin et al. disclose a method of forming at least partially solid material by subjecting a liquid at an outlet (col. 6, line 56) to an electric field causing the liquid to form at least one jet of electrically charged liquid, the liquid being such that after formation, the jet forms a fiber (col. 1, lines 13-23).

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As to applicant's recitation "to provide nuclei or otherwise initiate interactive cellular and/or molecular events in tissue repair", the applicant is directed to col. 2, lines 12-17, which recites "[w]here the dressing is formed from a wettable polymer, blood or serum escaping from the wound tends to penetrate the dressing and the high surface area encourages clotting. Such dressing may be used as emergency dressings to halt bleeding." This disclosure clearly meets the limitation of initiating interactive molecular events in tissue repair.

#### Allowable Subject Matter

8. Claims 47-49, 65-67, 69-75, 77-80 are allowed.

#### Response to Arguments

9. Applicant's arguments filed 2/22/05 have been fully considered but they are not persuasive. Regarding claim 61, the applicant argues that Coffee (instant invention) is different and distinguishable. More specifically, the applicant argues that.

"In addition to the important feature of not teaching electret polymers, Martin may first use any suitable polymer that will enable mechanical wetting alone. Or, in the case of a non-wetting polymer, provide small interstices. Thus, Martin is concerned with wettable polymers or small interstices. The quoted recitation of claim 61, in contrast, provides fibres, fibre fragments, or particles which "initate interactive cellular and/or molecular events". See, ¶ [0016] ("to promote essential cell activities, for example, to stimulate dendritic growth, growth factors such as fibroblast growth factor (FGF), epithelial growth factor (EGF), transforming growth factor (TGF) and others that may be used to promote or otherwise control the sequence of events essential to natural tissue repair") and ¶ [00711] (same quote). In addition, Martin teaches only encouraging clotting which, in turn, promotes tissue repair. The effect of the mat in Martin is, thus, as an indirect promoter of tissue repair. The effect of the mat in Martin is to encourage clotting, to stop bleeding, and perhaps, create and environment which may be favorable to tissue repair. As cited in claim 61, molecular events in tissue repair are initiated. Thus, new tissue is generated, at the molecular level, due to the presence of the formed fiber, fibrils, or particles of the electret polymer. Nothing in Martin teaches such effects from an electret polymer. In further support of these contentions, Applicant submits the enclosed Rule 132 Affidavit of Dr. Herbert S. Bresler. Accordingly, Applicant submits that claim 61 distinguishes patentably over Martin."

In response, the applicant should note that the polymer used in Martin et al. is inherently an electret polymer, and as admitted by applicant, "Martin teaches only encouraging clotting which, in turn, promotes tissue repair". Even if the accomplished feat of promoting tissue repair is an indirect result of applying the dressing of Martin et al. to a wound of user, the claimed limitation of initiating interactive cellular and/or molecular events in tissue repair is nevertheless accomplished.

#### Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kim M. Lewis—— Primary Examiner Art Unit 3743

kml June 14, 2005